

Applicable Drugs: Sprycel (dasatinib)

Preferred: dasatinib (generic)

Non-preferred: Sprycel (brand)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/4/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of one of the following indications A through B AND must meet all criteria listed under applicable diagnosis

FDA-Approved Indication(s)

A. Chronic myeloid leukemia (CML)

- i. Documentation of Philadelphia chromosome-positive (Ph+) or BCR-ABL1 kinase positive disease and meets criteria 1 or 2:

1. Documentation disease is in chronic phase and meets criteria a or b:

a. Age ≥ 1 to < 18 years old

b. Age ≥ 18 years old

i. Dasatinib is being used for first line therapy.

2. Documentation disease is in chronic, accelerated, myeloid, or lymphoid blast phase.

a. Documented resistance or intolerance to prior therapy, including imatinib.

B. Acute lymphoblastic leukemia (ALL)

- i. Documentation of Philadelphia chromosome-positive (Ph+) or BCR-ABL1 kinase positive disease and meets criteria 1 or 2:

1. Age ≥ 1 to < 18 years old

a. Dasatinib is being used for first line therapy in combination with chemotherapy.

2. Age ≥ 18 years old

a. Documentation of resistance or intolerance to prior therapy.

Other Uses With Supportive Evidence

C. Chondrosarcoma

D. Chordoma

- E. Gastrointestinal stromal tumor (GIST)
 - F. Myeloid/Lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions (MLNE)
 - G. Cutaneous Melanoma
 - H. CAR T-cell related toxicities
- II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
 - III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
 - IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- BCR-ABL-1 kinase domain mutational analysis showing T315I/A, F317L/V/I/C, or V299L mutations.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to sufficient tablets to fulfill a 30-day supply.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

Table 1. Sprycel dosage by indication¹⁻⁴

Indication	Dosage
ALL	• ≥1 to <18 years old: ○ 10 to < 20 kg: 40 mg orally once daily ○ 20 to < 30 kg: 60mg orally once daily ○ 30 to < 45 kg: 70 mg orally once daily ○ ≥ 45 kg: 100 mg orally once daily • ≥ 18 years old: 140 mg to 180 mg orally once daily

CML	Chronic Phase: • ≥ 1 to < 18 years old: ○ 10 to < 20 kg: 40 to 50 mg orally once daily ○ 20 to < 30 kg: 60mg to 70 mg orally once daily ○ 30 to < 45 kg: 70 to 90 mg orally once daily ○ ≥ 45 kg: 100 mg to 120 mg orally once daily • ≥ 18 years old: 100 mg to 140 mg orally once daily Chronic, accelerated, myeloid or lymphoid blast phase CML with documented resistance or intolerance to prior therapy: • ≥ 18 years old: 140 mg to 180 mg orally once daily
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.